



USSN: 10/054,710

Atty. Dkt. No.: 047940-0119

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

**Applicant:** Koichi MASUDA *et al.*

**Title:** TISSUE ENGINEERED CARTILAGE FOR DRUG DISCOVERY

**Appl. No.:** 10/054,710

**Filing Date:** 01/22/2002

**Examiner:** Ruth A. Davis

**Art Unit:** 1651

**DECLARATION UNDER 37 C.F.R. § 1.132 OF KOICHI MASUDA**

I, Koichi Masuda, state and declare that:

1. I am a citizen of Japan and a resident of the United States, residing at 827 Lavergne Avenue, Wilmette, Illinois, 60091.

2. I am an Associate Professor in the Orthopedic Surgery and Biochemistry Departments at Rush University Medical Center located in Chicago, Illinois.

3. I have a medical degree and 20 years of experience studying cartilage and artificial cartilage tissue. Given my experience and background, I believe that I possess at least a level of ordinary skill in the art.

4. I am a co-inventor of U.S. Application Serial No. 10/054,710 ("the application") and of U.S. Patent No. 6,197,061 ("the '061 Patent"). I have reviewed the Office Action, mailed December 23, 2004, and the prior art cited therein including the '061 Patent.

5. Until the discovery claimed in the present application we did not realize that our research would lead to a high throughput screening method of testing test agents on cartilage tissue. We did not appreciate that the cartilage tissue of the '061 patent could be cultured to be rapidly degraded, losing roughly half of its proteoglycan content within 24 hours following contact with a test agent. Unlike the artificial cartilage tissue in the present

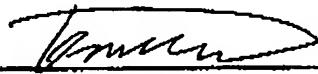
application, the tissue in the '061 patent may be matured to a point where the tissue would not work in the invention of the application because proteoglycan degradation would take several days.

6. In addition, we did not recognize that the methods used in this application afforded the current level of sensitivity following administration of a test agent. In the application, because of the increased sensitivity, the proteoglycan degradation may be measured without the present of radioactivity. Nothing in the tissue of the '061 patent suggests that this level of sensitivity can be obtained. In fact, in cartilage explants known at the time of the invention of the application, measurement of proteoglycan degradation required radioactivity.

7. Our invention is now being used by a private sector company which has licensed our technology.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent resulting therefrom.

Date: 3-19-05

By: 

Koichi Masuda